UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v. Case No. 13-CV-00990

SYLVIA BURWELL,
Secretary of the U.S. Department of Health
and Social Services,

Defendant.

**BRIEF IN SUPPORT OF PLAINTIFF'S REQUEST FOR JUDICIAL REVIEW**

## I. INTRODUCTION

The issue before this Court is narrow: Is the final decision of Defendant, the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), refusing to cover claims for a continuous glucose monitor and related supplies provided to Ms. Jill Whitcomb, a Medicare beneficiary, arbitrary and capricious and not otherwise supported by substantial evidence?

The answer is clear - The Secretary has a binding national coverage decision ("NCD") that explicitly covers home blood glucose monitors and her Medicare Administrative Contractor ("MAC") has issued a local coverage determination ("LCD"), further articulating coverage criteria which Ms. Whitcomb satisfies. Plaintiff Jill Whitcomb seeks an order from this Court finding that the Secretary's denial is not supported by substantial evidence and is arbitrary and capricious and ordering coverage of Ms. Whitcomb's continuous glucose monitor and related supplies in accordance with the Secretary's NCD and the MAC's LCD. If this Court determines that the NCD is not binding, and the MAC's discretionary LCD does not provide coverage, Ms.

Whitcomb requests that the Court find that the continuous glucose monitor ("CGM") is reasonable and necessary for Ms. Whitcomb in view of her critical medical condition supported by the administrative record ("A.R.") and which is unrefuted, and which the Secretary failed to address in her denial. Finally, if this Court deems the CGM not covered by Medicare, Whitcomb seeks an order from this Court that payment is due under 42 U.S.C. § 1395pp because Ms. Whitcomb could not have reasonably known the CGM and related supplies would not be covered.

## II. STATUTORY AND REGULATORY BACKGROUND

### A. General Background of the Medicare Program

The Medicare Act establishes a program of health insurance for the aged, disabled, and individuals with end-stage renal disease. 42 U.S.C. §§ 1395-1395ccc. Medicare includes Parts A through D. This action arises under Part B, which generally covers non-institutional claims. The Secretary, the Federal official responsible for administering the Medicare program, has delegated that responsibility to the Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS. CMS has contracted out many Medicare administrative functions, including payment, to private organizations. *See, e.g.*, 42 U.S.C. § 1395h. MACs are contractors who, among other things, process claims and set policy for a particular geographic region.

### B. Notice and Comment Rulemaking Required

Under 42 U.S.C. § 1395hh(a)(1), the Secretary is required to "prescribe such regulations as may be necessary to carry out the administration" of the Medicare program. It statute also states:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). 42 U.S.C. § 1395hh(a)(2).

The Secretary has elected to publish many rules implementing the Medicare program in various manuals, such as the Medicare Program Integrity Manual and the Medicare Claims Processing Manual ("MCPM"). Under 42 U.S.C. §1395hh(a)(2), however, these manual provisions are not promulgated in accordance with the notice and comment provisions of the APA and thus are not effective to "establish or change a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits" under Medicare.

### C. Medicare Coverage and Payment of Home Blood Glucose Monitors

A National Coverage Determination ("NCD") is "a determination by the Secretary that a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a)(1). An NCD is binding on all Medicare contractors, administrative law judges ("ALJs") and the Medicare Appeals Council ("Council"). 42 C.F.R. § 405.1060(a)(4). Medicare has covered glucose monitors under NCD 40.2 since at least 1995. NCD 40.2 has been expanded over the years to provide coverage for a larger population of diabetics (e.g., it was expanded to include those who are not insulin dependent, but are being treated with insulin).

### D. Local Coverage Determinations and Articles

Where CMS has established a national coverage policy, a Medicare contractor processing the claim may, but is not required to, establish a local coverage determination ("LCD") that applies to the claims processed by that contractor. An LCD may not conflict with an NCD. LCDs are based on the peer-reviewed literature and general acceptance by the medical community. See Medicare Program Integrity Manual ("MPIM"), Ch. 13, §13.7.1.[1] LCDs are developed in consultation with the relevant medical community. MPIM, Ch. 13, §§13.7 and 13.8. An LCD

[1] Chapter 13 of the MPIM, entitled "Local Coverage Determinations" is being submitted as Attachment A. The MPIM is updated regularly and the 04/11/14 revision is being submitted. None of the provisions that apply to this case have changed since the ALJ hearing and the MAC decision.

that is contrary to the standard of care must be based on sufficient evidence to convincingly refute evidence presented in support of coverage. Attachment A - MPIC, Ch. 13, §13.8.

Consistent with the NCD, the relevant MAC, National Government Services ("NGS") issued an LCD indicating the coverage criteria for blood glucose monitors and related supplies.[2] The LCD does not indicate continuous glucose monitors are not a covered service. LCDs are not binding on an ALJ although they are entitled to deference. 42 C.F.R. § 405.1062(a). An ALJ can decline to follow an LCD if the ALJ provides a rationale.

"Articles" are informal communications issued by MACs without consultation with the relevant medical community, typically addressing billing or coding issues, not coverage. Articles, by design, do not contain coverage determination – only non-reasonable and necessary language can be communicated through articles. See http://cms.hhs/Medicare-coverage-database.gov (accessed on Oct. 19, 2014). Billing guidance explicitly is not a coverage policy. Because they should not contain coverage information, Articles are not subject to challenge by Medicare beneficiaries. 42 C.F.R. 426.325(b)(9). Under Medicare regulations, a MAC's Article is not entitled to any deference.[3] Effective January 1, 2007, NGS modified Article A47238, an article on glucose monitors, stating it considered CGM "precautionary."

### E. Medicare Advantage Plans

Medicare Advantage Organizations ("MAOs") offer health insurance plans that cover at least all services, devices and supplies a Medicare beneficiary is entitled to receive under Medicare Parts A and B. Claims for payment for devices and supplies provided to Medicare beneficiaries are presented to MAO for claims processing. The MAO is bound to cover all items covered

[2] NGS LCD 27231.
[3] Unlike LCDs, which must be developed only after consultation with the relevant local medical community (MPIM Ch. 13, § 13.7.1 – Attachment A), articles do not require consultation to be published, are not subject to challenge, and are entitled to no deference. 42 C.F.R. §426.325(b)(9).

through an NCD and/or LCD. United Healthcare of Wisconsin/Secure Horizons (hereinafter "United") is an MAO. MAOs are charged with knowing the standard of care. MAOs also are charged with knowing Medicare coverage policies and the distinction between LCDs and Articles. United's agreed that its Evidence of Coverage does not specifically mention continuous glucose monitoring (A.R. at 885 and 886), but it does indicate that it covers glucose monitors. A.R. at 647, 802 and 812.[4]

**F. Appeals of Medicare Claims Decisions**

Congress has established a five-step process for a Medicare beneficiary to follow to obtain judicial review when she is dissatisfied with the Secretary's coverage determination of a claim for a device and supplies. The first step in the process is to request redetermination by the MAC/MAO that made the initial determination on the claim. 42 C.F.R. §§ 405.940-405.958. Under 42 C.F.R. § 405.956(b), the redetermination notice issued by the MAC/MAO must include, *inter alia*, (a) a summary of the clinical or scientific evidence used in making the redetermination, (b) an explanation of relevant laws, regulations, coverage rules, and/or CMS policies that apply to the case, and (c) a summary of the rationale for the redetermination in clear, understandable language. 42 C.F.R. § 405.956(b). The redetermination process is non-adversarial and no hearing is offered. 42 C.F.R. § 405.948.

If a beneficiary is dissatisfied with a MAC's redetermination decision it may request reconsideration by the qualified independent contractor ("QIC"). 42 C.F.R. § 405.960. The QIC must review the record of the claim and, without holding a hearing, issue a reconsideration decision having the same decision elements as the MAC/MAO's redetermination decision. 42 C.F.R. § 405.976(b). If the appeal involves medical necessity, the QIC is required to use a panel

[4] But see Coverage Summary at A.R. 572- 573, acknowledging no applicable NCD or LCD, and providing for short term coverage for CGM.

of physicians or other "appropriate health care professionals" to render a decision. 42 C.F.R. § 405.968(a). The QIC is required to have knowledge of the standard of care when adjudicating claims. The QIC reconsideration is non-adversarial and the decisions are non-precedential. 42 C.F.R. § 405.968.

If the QIC decision is unfavorable, the beneficiary may appeal the QIC's decision by requesting a hearing before an ALJ. 42 C.F.R. § 405.1000. After review of the record forwarded by the QIC, and any additional evidence offered by the parties which the ALJ makes part of the record, the ALJ conducts a hearing. 42 C.F.R. §§ 405.1000 *et seq*. The ALJ's decision must be based on the evidence in the administrative record. 42 C.F.R. § 405.1046. An MAO is always a party to an ALJ hearing involving a claim it denied and may present witnesses in support of its denial decision. An ALJ is bound to follow an NCD and must give deference to an LCD or explain why the LCD was not followed. "[A]n ALJ may rule that Medicare payment is due on a particular item or services received by a beneficiary, based on the particular circumstances represented by the case, even if the contractor's . . . LCD clearly prohibits payment for the particular services." 68 Fed. Reg. 63693 (Nov. 7, 2003). Although ALJ hearings are generally non-adversarial, CMS may intervene as a party.[5] 42 C.F.R. § 405.1037(a).

An MAO may appeal an ALJ decision to the Medicare Appeals Council ("Council"). 42 C.F.R § 405.1102. Again, an NCD is binding on the Council. 42 C.F.R. § 405.1060(a)(4). The Council limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. 42 C.F.R. § 405.1122(a). The Council limits its review of an ALJ's decision to those exceptions raised by the party in the request for review. 42 C.F.R § 405.1112(c). The Council typically does not conduct a hearing or allow oral argument, but has

[5] CMS did not intervene as a party in the decision at issue here.

discretion to do so.[6] 42 C.F.R. § 405.1124. The Council's decision is the Secretary's final agency decision for purposes of judicial review. 42 U.S.C. §§ 1395ff(b) and 405(g).

The Secretary's decisions are reviewed under the APA standard and must be based on substantial evidence in the record and must not otherwise be arbitrary, capricious, or an abuse of discretion. 42 C.F.R. § 405.1136(f). The Secretary is responsible for filing a copy of the administrative record with the Court and certifying to its completeness. 42 U.S.C. § 405(g).

### G. Limitation of Liability

Under the "limitation of liability" provisions of the Medicare Act, codified at 42 U.S.C. §1395pp, when the Secretary has determined that an item or service is not medically necessary under 42 U.S.C. § 1395y(a)(1), the Medicare program will, nevertheless, make payment for the item or service if the supplier and beneficiary "did not know and could not have been expected to know" that Medicare would not make payment. The applicable statute states that Medicare will make payment, and providers and beneficiaries will be held harmless:

> Where - (1) a determination is made that, by reason of section 1395y(a)(1) . . . , payment may not be made under part A or part B of this subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395u (b)(3)(B)(ii) of this title, and
>
> (2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B of this subchapter . . . . 42 U.S.C. § 1395pp(a)(1) and (2).

The applicability of 42 U.S.C. § 1395pp also is clear from the Secretary's implementing regulations, which set forth the criteria for determining whether a provider "knew or could have been expected to know" that the services were excluded from coverage. That regulation states that a provider will be deemed to have knowledge of non-coverage under the following criteria:

[6] The Medicare Appeals Council did not conduct a hearing for the decision at issue in this action.

> (e) Knowledge based on experience, actual notice, or constructive notice. It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:
>
> (1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, . . ..
>
> (2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding noncoverage of an item or service.
>
> (3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

42 C.F.R. § 411.406(e). Criteria (1) and (2), which address notices issued by CMS, or published by the Secretary in the Federal Register, support coverage. The NCD and LCD clearly indicate that home blood glucose monitors are covered. No exclusion is made for CGM.

## III. STATEMENT OF FACTS – CGM

Many diabetics manage their disease by finger stick glucose monitoring and subcutaneous injections of insulin. However, a segment of the diabetic population cannot control their diabetes through conventional care and suffer significant complications including stroke, loss of consciousness, retinopathy, nephropathy and neuropathy. Uncontrolled diabetes is the number one cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults. A.R. at 149. (A.R. refers to the Administrative Record - Docket #18 and #34.)

A continuous glucose monitor uses a cannula that is inserted into interstitial fluid and senses blood sugar levels every five minutes. A.R. at 830. A CGM can identify blood glucose excursions by providing 288 glucose values per day. A.R. at 144. A CGM alerts patients when their blood glucose levels are out of range so that the patients can take action to control their blood glucose. CGM has been the subject of multiple published peer-reviewed clinical studies, including large multi-center trials, all of which found improved clinical outcome for the patients.

United notes that CGM provides "the ability to monitor diabetic control in patients who have proven refractory to conventional self- monitoring." A.R. at 572. Further, United notes that CGM is of "specific value in those patients who have wide glycemic swings, frequent hospitalizations and complications of their systemic illness." *Id.*

## IV. STATEMENT OF FACTS – ADMINISTRATIVE PROCEEDINGS

Ms. Whitcomb was prescribed a CGM to enable her to better manage her Type 1 diabetes mellitus. United denied the claim and upheld the denial on redetermination citing Article A47238. Ms. Whitcomb appealed the denial to Maximus which in June 2012, also denied the claim citing Article A47238. Despite the requirement of clinical review, the QIC decision is not signed by any clinician and the denial is premised solely on Article A47238. Ms. Whitcomb timely appealed to an ALJ. Judge Bush conducted a hearing on October 15, 2012 and December 31, 2012. Ms. Whitcomb, her caregiver Daniel Kraft, and nurse practitioner Nicole Schneider provided testimony in support of coverage. Dani Collier, who has no medical credentials, testified on behalf of United. Ms. Whitcomb also submitted medical records and a video of a recent emergency visit in support of her claim. A.R. at 155.

In his February 6, 2013 Fully Favorable Decision ("ALJ Decision"), Judge Bush reviewed the NCD and noted he was bound to follow it. ALJ Decision at 10, A.R. at 77. He also found LCD L27231 provided coverage for glucose monitors and Ms. Whitcomb satisfied its coverage criteria. ALJ Decision at 10 and 11, A.R. at 77- 78. Although not he was not required to give Article A47238 deference because it is not an LCD, Judge Bush indicated he would not follow it for another reason, Ms. Whitcomb's clearly demonstrated medial need. He noted her frequent episodes of hypoglycemia supported by the medical records, her emergency room visits, and her dangerously low blood sugar level of 13. (Blood sugars should be between 70 and 160. At 13,

an individual typically is unconscious.) He noted that without CGM, Ms. Whitcomb would have frequent hypoglycemic events requiring emergency room visits and hospitalizations. ALJ Decision at 10, A.R. at 77. He further noted that with CGM, Ms. Whitcomb was much better able to manage her diabetes. Judge Bush found the CGM was reasonable and medically necessary for Ms. Whitcomb and coverage of it was consistent with NCD 40.2 and LCD L27231. ALJ Decision at 11, A.R. at 78.

United appealed the ALJ Decision. Ignoring the ALJ's findings that CGM would be covered by Medicare for Ms. Whitcomb, United asserted that CGM was not covered by "Original Medicare." United conceded that although CGM "may be useful" to Ms. Whitcomb, it would not cover it. The Council asserted the NCD does not explicitly address CGM. Although United conceded no LCD excluded CGM (A.R. at 887), the Council elevated Article A47238 to LCD status and stated the Article explicitly excludes CGM coverage. Ignoring the ALJ's specific recitation of Ms. Whitcomb's medical condition and reasons why he did not defer to the Article, the Council found, "The record contains insufficient evidence to support departing from the non-coverage of continuous glucose monitor systems." A.R. at 28.

By this action, Ms. Whitcomb seeks judicial review of the August 23, 2013 Council decision regarding ALJ appeal number 1-1012671541 (the "Decision"). Below, we set forth the uncontradicted support in the A.R. showing that the CGM for Ms. Whitcomb is properly covered by Medicare and request that the Court reverse the Secretary's finding and order coverage.

## V. STANDARD OF REVIEW

Under the Medicare statute, 42 C.F.R. § 1395ff(b), the final agency decisions included in this action are subject to judicial review under the applicable provisions of the APA. *Heart 4 Heart, Inc. v. Sebelius*, 2014 WL 3028684, *5 (C.D. Ill. 2014) (treating submission as request to review

decision by MAC rather than summary judgment motion). Accordingly, this Court's review of the Secretary's actions is governed by 5 U.S.C. § 706 of the APA, which requires the Court to determine whether, *inter alia*, her actions are arbitrary and capricious, an abuse of discretion, not based on substantial evidence, or otherwise not in accordance with law. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414-17 (1971). If so, the Court must set it aside.

In *Motor Vehicle Manufacturers Ass'n of the United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Supreme Court described the "arbitrary and capricious" standard as follows:

> Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

*Id*. at 63. Similarly, the "substantial evidence" standard requires an in-depth review of the facts relied upon by the agency in its decision:

> A 'substantial evidence' standard, however, does not permit a court to uphold the Secretary's decision by referring only to those parts of the record which support the [Secretary]. A reviewing court must view the entire record and take account of evidence in the record which detracts from the evidence relied on by the [Secretary].

*Tieniber v. Heckler*, 720 F.2d 1251, 1253 (11th Cir. 1983); *accord Brown v. Bowen*, 794 F.2d 703, 705 (D.C. Cir. 1986) ("Our review in substantial-evidence cases calls for careful scrutiny of the entire record.").

"Substantial evidence means 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Clifford v. Apfel*, 227 F.3d 863, 869 (7th Cir. 2000), quoting *Richardson v. Perales*, 402 U.S. 389, 491 (1971). Reviewing courts do not reweigh the evidence. "However, this does not mean that we will simply rubber-stamp the Commissioner's decision without a critical review of the evidence." *Clifford v. Apfel*, at 869 (citations omitted).

It is well established "that an agency must cogently explain why it has exercised its discretion in a given manner and that explanation must be sufficient to enable us to conclude that the [agency's action] was the product of reasoned decisionmaking." *U.S. Telecom Ass'n v. FCC*, 227 F.3d 450, 460 (D.C. Cir. 2000)." A reviewing court may uphold agency action only on the basis articulated by the agency in its decision, not on *post-hoc* rationalization offered by the agency or its counsel. *Roddy v. Astrue*, 705 F.3d 631,636, 637 (7th Cir. 2013) citing *SEC v. Chenery Corp*., 318 U.S. 80, 87-88 (1943); *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 631 n.31 (1980); *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 169 (1962); *Biloxi Regional Medical Center v. Bowen*, 835 F.2d 345, 348 n.12 (D.C. Cir. 1987). The Seventh Circuit has been especially vigilant in applying *Chenery*.

Although deference to the Secretary's actions may be appropriate under certain circumstances, such deference is inappropriate here because Secretary misapplied the Article, did not apply the NCD and LCD and her numerous public statements, failed to consider the patient's medical condition and denied coverage despite covering CGM for medically indistinguishable Medicare beneficiaries. In *Malcomb v. Island Creek Coal Co*., the court stated:

> An agency's interpretation of its own regulations is normally entitled to judicial deference. We accord this deference to the agency's interpretation even if the agency has made considered changes in that interpretation because '[a]n initial agency interpretation is not instantly carved in stone' and the agency should be free to 'consider varying interpretations and the wisdom of its policy on a continuing basis.' When the agency's varying interpretations of a regulation have not been the result of the agency making considered changes in its policy, but rather of the agency simply acting inconsistently without explanation, however, 'the case for judicial deference is less compelling.' ***Moreover, if the agency's record of unexplained inconsistent interpretation is particularly egregious, the interpretation that the agency applied in the case before the court is entitled to no deference***.

15 F.3d 364, 369 (4th Cir. 1994) (emphasis added; citations omitted). In reversing the government, the Fourth Circuit continued: "We find the interpretation of its cross-appeal

regulations that the Board applied in the case at bar to have been shockingly inconsistent with its prior and subsequent interpretations." *Id.*

Finally, no deference is due to the Secretary's Decision if it conflicts with the Secretary's binding NCD 40.2. See *Sierra Club v. Martin*, 168 F.3d 1, 4 (11th Cir. 1999) (no deference due to agency action which does not follow the agency's own regulations); see also *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504 (1994) (no deference due to agency interpretation that contradicts the regulation's plain language.); see also *University Health Servs. v. HHS*, 120 F.3d 1145, 1149 (11th Cir. 1997) ("The Secretary's interpretation of her own regulations are 'controlling unless plainly erroneous or inconsistent with the regulation.'") (citations omitted).

## VI. ARGUMENT

The Decision contains fundamental errors. First, the Secretary improperly equates the Article with an LCD and improperly accords it deference. Second, the Secretary failed to consider the evidence that supported coverage of CGM even if the Article had been an LCD and entitled to some deference. The Decision is not supported by substantial evidence and is contrary to the overwhelming evidence in the record. The Secretary has paid for CGM for medically indistinguishable beneficiaries. Despite the Secretary's NCD and numerous public statements regarding the need for diabetics to test frequently and control their diabetes, the Secretary denied the claim for a Medicare beneficiary who was trying to do exactly that and who is otherwise unable to control her diabetes and complications therefrom. As explained below, the Secretary's reasons for denying the claims at issue lack a basis in law and fact and must be reversed.

### A. The Article is Not an LCD and is Not Entitled to Deference

Throughout her Decision the Secretary improperly equates the Article with an LCD. As noted above, an article explicitly is not a coverage policy. Further, contrary to the Secretary's

assertion, the LCD does not incorporate the Article by reference. Rather, the LCD simply identifies the Article as a "Related Document." A.R. 586. Even if the LCD had incorporated the Article by reference, the Article would not be entitled to the same deference as an LCD because articles are not based on peer-reviewed literature, consultation with the relevant medical community or with consideration of standards within the relevant medical community. Attachment A - MPIM Ch. 13, §13.7.1. If articles were accorded the same status as an LCD, MACs could change Medicare coverage policy without following the process prescribed by Medicare regulations and could avoid having such policy changes challenged through the LCD challenge process. Thus, because the sole basis of the Secretary's Decision (and that of United and the QIC) is based on her improper elevation of an article to LCD status, it must be set aside as contrary to the law.

Finally, even if Article A47238 enjoyed LCD status, which it does not, as Judge Bush recognized, based on the overwhelming evidence in the administrative record, he determined not to apply Article's unsupported and unsupportable statement regarding the "precautionary" nature of CGM, and explained his rationale therefore. A.R. at 52. In contrast, as described more fully below, the Secretary failed to consider the evidence in the administrative record.

### B. The Lack of Medical Reasonableness and Necessity is Not Supported by Substantial Evidence

#### 1. Ms. Whitcomb's Medical Condition Warrants CGM

Ms. Whitcomb has a clearly demonstrated need for CGM. The unrefuted, overwhelming evidence in the A.R. establishes that CGM was and is reasonable and necessary for Ms. Whitcomb, a brittle diabetic who suffers from hypoglycemia, has frequent glucose swings, despite frequent testing cannot detect glucose lows, and suffers significant complications resulting in significant cost to Medicare. No clinician reviewing Ms. Whitcomb's record opined

that she did not have a dire need for CGM. As Judge Bush found, Ms. Whitcomb's dire need for the CGM is well supported by the submitted medical records. The Administrative Record includes the following unrefuted facts:

> •Ms. Whitcomb's blood glucose level can significantly change in a period as short as ten minutes. A.R. at 890.
>
> •Ms. Whitcomb has hypoglycemia which means she cannot detect a sugar low, an extremely dangerous condition. A.R. at 827.
>
> •Ms. Whitcomb repeatedly has been discovered passed out on the floor because of her inability to detect low blood glucose. A.R. at 144; A.R. at 155, CD 5:55-8:29.
>
> •Ms. Whitcomb has passed out in bed several times while sleeping. A.R. at 322-327.
>
> •Ms. Whitcomb had been admitted to the emergency room numerous times because despite frequent monitoring, she cannot detect changes in her glucose. A.R. at 835.
>
> •Medicare has paid than $14,000 for emergency room visits associated with Ms. Whitcomb's hypoglycemia unawareness and gastroparesis. A.R. at 155, CD 6:11-6:20.
>
> •Ms. Whitcomb's diabetes with hypoglycemia is so severe that she is on disability. A.R. at 888.
>
> •CGM provided a "vast improvement" of Ms. Whitcomb's blood glucose control and resulted in substantially fewer hypoglycemic events. A.R. at 144.
>
> •The QIC acknowledged that Ms. Whitcomb has poorly controlled diabetes with frequent hypoglycemic episodes. AR. at 256.
>
> •United concedes that Ms. Whitcomb tests her blood sugar at least 10 times daily. A.R. at 256.

Nonetheless, for the claim at issue in this action, the Secretary denied coverage because she found that CGM was not reasonable or necessary for Ms. Whitcomb. A.R. at 26-27.

Substantial evidence does not exist in the administrative record to refute the documentary and testimonial medical evidence supporting Ms. Whitcomb's dire medical need for CGM. In fact, no evidence supports the denial. The Secretary simply did not discuss Ms. Whitcomb's medical condition, her inability to detect glucose lows without the CGM, the significant

complications that can and have devolved from her hypoglycemic unawareness, her significantly improved control with CGM, and the significant cost to Medicare when Ms. Whitcomb is unable to control her diabetes. The ALJ had discussed this evidence and relied on it. The Secretary's Decision failed to even acknowledge this contrary evidence which "detracts" from the conclusion regarding non-coverage. *Tieniber v. Heckler*, 720 F.2d at 1253 (11th Cir. 1983). Not only did the Secretary not discuss the foregoing, but she did not discuss a reason for rejecting the opinion of Ms. Whitcomb's physicians and providers.

**2. The Uncontroverted Evidence from the Treating Practitioners Shows that the CGM is Medically Reasonable and Necessary**

In CMS Ruling 93-1, issued on May 18, 1993, the Secretary addressed the applicability of the "treating physician's rule" in Medicare cases. The CMS Ruling states, in pertinent part, as follows: "The final determination by the medical review entity should not be based solely on the physician's opinion, but should reflect its evaluation of all documentation contained in the medical record." Accordingly, where the treating physician's opinion is supported by the documentation in the medical record, it may not be rejected by the Secretary for Medicare purposes. Several courts have elaborated on the treating physician rule in the context of Medicare cases. In *Klementowski v. Secretary of HHS*, 801 F. Supp. 1022 (W.D.N.Y. 1992), the court summarized the rule as applied in the Social Security disability setting, as follows:

> The treating source's opinion on the subject of medical disability--*i.e.*, diagnosis and nature and degree of impairment--is (1) binding on the fact-finder unless contradicted by substantial evidence and (2) entitled to some extra weight, even if contradicted by substantial evidence, because the treating source is inherently more familiar with a claimant's medical condition than are other sources.

*Id.* at 1025. citing, *Schisler v. Bowen*, 851 F.2d 43, 47 (2nd Cir. 1988).

The court in *Klementowski* acknowledged that the treating physician rule did not have the same presumption in Medicare cases that it does in Social Security determinations. However, the

court cited *State of New York v. Sullivan*, 927 F.2d 57 (2d Cir. 1991) for the proposition that the Secretary should place significant reliance on these opinions giving them extra weight or providing a reasoned basis for failing to do so. The *Sullivan* case said:

> Though the considerations bearing on the weight to be accorded a treating physician's opinion are not necessarily identical in the disability and Medicare contexts, we would expect the Secretary to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of 'some extra weight,' to be accorded to that opinion ... or to supply a reasoned basis, in conformity with statutory purposes for declining to do so.

927 F.2d at 60. Many courts have recognized that the treating physician rule should apply with equal force in Medicare case. As one court explained,

> It is a well-settled rule in Social Security disability cases that the expert medical opinion of a patient's treating physician is to be accorded deference by the Secretary and is binding unless contradicted by substantial evidence. This rule may well apply with even greater force in the context of Medicare reimbursement. The legislative history of the Medicare statute makes clear the essential role of the attending physician in the statutory scheme: "The physician is to be the key figure in determining utilization of health services."

*Gartmann v. Secretary of U.S. Dept. of Health and Human Services*, 633 F. Supp, 671, 680-681 (E.D. N.Y. 1986), quoting, 1965 U.S. Code Cong. And Ad. News, 1943, 1986.[7] This is especially compelling where, as here, there is "no direct conflicting evidence." *Kuebler v. Secretary of U.S. Dept. of Health & Human Services*, 579 F. Supp. 1436 (D.C. N.Y. 1984). Because CMS has never adopted specific regulations specifying what might constitute medical necessity in each case, reliance on a treating physician's opinion of medical necessity is even more important than in the Social Security context:

[7] *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 830 (2003), held that the treating physician rule did not apply to discretionary determinations made by an ERISA plan, but noted its application to administrative rule-based determinations in cases involving Social Security, Longshoreman's benefits and the Black Lung Benefits Act. While the Supreme Court did not decide the question, Medicare cases are in the same administrative realm as the other types of case in which the treating physician rule does apply. Even in ERISA cases, the decision-maker may not ignore evidence from the patient's treatment providers. *Leger v. Tribune Co. Long Term Disability Benefit Plan*, 557 F.3d 823, 834 (7th Cir. 2009).

> CMS has not delineated what constitutes "medically indicated" and "necessary" items or services furnished to Medicare patients and the specific documentation required to support medical necessity in individual cases. In determining medical necessity, courts employ what is known as the "treating physician" rule, which provides that with respect to medical necessity, the judgment of the treating physician should be given "extra weight" or "a reasoned basis . . . [should be supplied] for declining to do so.

*U.S. v. Prabhu*, 442 F. Supp.2d 1008, 1032 (D. Nev. 2006).

The Secretary should not reject the opinion of a claimant's physician without clear and convincing evidence to do so and that her interpretation should not be given unbridled deference:

> [W]e see no reason why we should accept [the Secretary's] opinion, . . . rather than that of the medical expert. Defining what is necessary medical treatment does not appear to be one of those areas in which the Secretary has sufficient expertise that we should give unbridled deference to her interpretation. . . . Outside of the Medicare context, in related areas, courts have concluded that physicians, not administrative agencies, have responsibility for determining what constitutes necessary medical treatment. . . . In the Social Security disability-compensation context, the ALJ can reject the opinion of the claimant's physician on the ultimate issue of disability only by presenting clear and convincing reasons for doing so.

*Vista Hill Foundation, Inc. v. Heckler*, 767 F.2d 556, 560-1 (9th Cir. 1985) (citations omitted). The Secretary's Decision in this case asserts that CGM is not medically reasonable and necessary. This lacks a basis in law and fact because a physician's determination of medical necessity cannot be simply rejected if it is supported by the medical record and not otherwise contradicted. *Id.*

The treating practitioners' opinions are supported by the medical record, there is no evidence to the contrary in the A.R., and the Secretary has failed to provide a "reasoned basis" for refusing to accept their opinions. *Heart 4 Heart, Inc. v. Sebelius*, 2014 WL 3028684, *8- 9. The treating practitioners' determinations stand as unrefuted, and, therefore, binding evidence of medical necessity. Accordingly, the Secretary has no legal or factual basis to deny payment for the CGM on the grounds that it is not medically reasonable and necessary.

Thus, even if CGM is "precautionary" for diabetics who are able to control their glucose through conventional testing and do not have hypoglycemic unawareness, CGM clearly is reasonable and necessary for Medicare beneficiaries like Ms. Whitcomb who are unable to control their diabetes without CGM and who have, and will continue to have, significant medical complications and costs associated therewith. On that basis, an exception to the Article, even if it was entitled to the deference accorded an LCD, was and is warranted. Certainly Ms. Whitcomb's need for CGM, based on unrefuted evidence in the A.R. and including the opinion of her treating practitioner, is supported while no evidence supports the Secretary's unexplained denial.

### C. The Decision is Arbitrary and Capricious Because it is Inconsistent with NCD 40.2, the Standard of Care and Previous Decisions.

Further, even if the Article is entitled to the deference accorded to an LCD, which it is not, the Secretary should have found an exception is warranted because: (1) it conflicts with the NCD 40.2; (2) it was issued without consideration of the peer-reviewed literature and government technology assessments; and (3) it conflicts with the standard of care. The NCD 40.2 explicitly covers glucose monitoring for diabetics. No exclusion is made for CGM.

Further, the Secretary's denial of the claim, and her Answer,[8] clearly indicates that the Secretary did not avail herself to agency expertise when rendering her Decision. CGM for diabetics who have hypoglycemic unawareness is well supported by the peer-reviewed literature,[9] recommended by virtually every professional medical organization responsible for treating such diabetics, is the standard of care recognized by private insurers,[10] and was deemed to be reasonable and medically necessary by a Federally-funded technology assessment. The

[8] The Secretary asserted she lacked sufficient information or knowledge regarding the various cited consensus statements of national and professional organizations recommending CGM, the federally funded technology assessment, and the widespread acceptance of CGM. Answer to Amended Complaint, Docket #33, at 7.
[9] A.R. at 849.
[10] A.R. at 844.

Secretary's Decision reflects neither awareness nor consideration of the relevant literature or norms.

In *Independent Petroleum Ass'n of Am. v. Babbitt*, 92 F.3d 1246, 1260 (D.C. Cir. 1996), the court stated:

> The treatment of cases A and B, where the two cases are functionally indistinguishable, must be consistent. That is the very meaning of the arbitrary and capricious standard.

The Secretary has ordered other MAO plans to pay claims for CGM for other Medicare beneficiaries whose medical condition is indistinguishable from Ms. Whitcomb's condition. (See e.g., ALJ No. 1-555141631, submitted as Attachment B). Indeed, Ms. Whitcomb has a more compelling clinical need for CGM than the claimant in that case. Thus, the Secretary's denial is arbitrary and capricious and must be reversed.

### D. Alternatively, Coverage of CGM Should Be Approved Under 42 U.S.C. §1395pp.

Medicare regulations, through the "limitation on liability" provisions, specifically protect Medicare beneficiaries in this precise situation. The "limitation on liability" provisions are straightforward, mandatory, and applicable here. Where the Secretary has determined that an item or service is not medically necessary under 42 U.S.C. §1395y(a)(1), the Medicare program will, nevertheless, make payment for the item or service if the beneficiary "did not know and could not have been expected to know" that Medicare would not make payment.

The applicable statute states that Medicare will make payment, and providers and beneficiaries will be held harmless:

> Where - (1) a determination is made that, by reason of section 1395y(a)(1) . . . , payment may not be made under part A or part B of this subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another

> person pursuant to an assignment under section 1395u (b)(3)(B)(ii) of this title, and
>
> (2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B of this subchapter . . . .

42 U.S.C. §1395pp(a)(1) and (2). By enacting42 U.S.C. §1395pp, Congress sought to protect Medicare beneficiaries from erratic and unpredictable behavior by the Secretary by requiring Medicare to make payment for the claims that the Secretary handles inconsistently, such as the ones at issue in this action.

The Secretary's Decision does not address how Ms. Whitcomb could have known that a device, which is recognized as the standard of care for individuals who have hypoglycemic unawareness, covered by most commercial payers, which her provider prescribed, which results in substantial medical improvement and Medicare cost-savings, and which coverage is at least implied in NCD 40.2, LCD 27231, and numerous public health statements, is not covered. Accordingly, pursuant to 42 U.S.C. §1395pp, this Court must order the Secretary to pay for Ms. Whitcomb's CGM.

## VII. CONCLUSION

The Secretary's Decision is contrary to law and unsupported by the facts. The Article is not an LCD and is entitled to no deference. Further, even if the Article had been an LCD, the ALJ recognized Ms. Whitcomb's dire medical condition, supported by the administrative record, and indicated he would not accord the Article deference. Based on Ms. Whitcomb's condition, the ALJ found that the CGM was reasonable and medically necessary, and covered by "Original Medicare" and thus ordered the MAO to cover it. The MAC Decision is not supported by the Administrative Record, or any relevant evidence, and it reflects the Secretary's failure to avail herself of agency

expertise and consider the unrefuted evidence in the A.R. in this case. The Decision is arbitrary and capricious as it conflicts with her NCD and her prior determinations regarding CGM. For the foregoing reasons, this Court should reverse the decision of the Medicare Appeals Council and direct the Defendant to cover Plaintiff Whitcomb's claim for a continuous glucose monitor and related supplies.

Date: October 30, 2014

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that, on the 30th day of October, 2014, I electronically filed Plaintiff's Motion for Summary Judgment, with supporting papers, using the Eastern District of Wisconsin CM/ECF system which will automatically send email notification of such filing to counsel of record for Defendant.

Date: October 30, 2014

/s/ Robert Theine Pledl

Robert Theine Pledl